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Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ZEBETA® (bisoprolol fumarate). ZEBETA® is indicated in the management of hypertension. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ZEBETA® (U.S. Patent No. 4,258,062) from E. Merck GmbH, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated November 13, 1992, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ZEBETA® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ZEBETA® is 2,874 days. Of this time, 1,778 days occurred during the testing phase of the regulatory review period, while 1,096 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective*: September 19, 1984. The applicant claims September 16, 1984, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 19, 1984, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: August 1, 1989. The applicant claims July 28, 1989, as the date the new drug application (NDA) for ZEBETA® (NDA 19–982) was filed. However, FDA records indicate that NDA 19–982 was submitted on August 1, 1989.

3. *The date the application was approved*: July 31, 1992. FDA has verified the applicant's claim that NDA 19–982 was approved on July 31, 1992.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 2 years of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 12, 1993, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before August 9, 1993, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 21, 1993.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 93–3050 Filed 2–8–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92E–0471]

Determination of Regulatory Review Period for Purposes of Patent Extension; Suprane™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Suprane™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nicholas P. Reuter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the

actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Suprane™. Suprane™ (desflurane) is indicated as an inhalation agent for induction or maintenance of anesthesia for inpatient and outpatient surgery in adults. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Suprane™ (U.S. Patent No. 4,762,856) from Anaquest, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated December 15, 1992, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Suprane™ represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Suprane™ is 1,369 days. Of this time, 771 days occurred during the testing phase of the regulatory review period, while 598 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective*: December 21, 1988. FDA has verified the applicant's claim that December 21, 1988, was the date the investigational new drug application became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: January 30, 1991. FDA has verified the applicant's claim that January 30, 1991, was the date the new drug application (NDA) for Suprane™ (NDA 20–118) was initially submitted.

3. *The date the application was approved*: September 18, 1992. FDA has verified the applicant's claim that NDA 20–118 was approved on September 18, 1992.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 406 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 12, 1993, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before August 8, 1993, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 21, 1993.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 93–3043 Filed 2–9–93; 8:45 am]

BILLING CODE 4160–01–F

Report of the FDA Task Force on International Harmonization; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report entitled "Report of the FDA Task Force on International Harmonization." This report provides an overview of FDA's international activities and describes the importance of international harmonization efforts as they affect the safety, effectiveness, and quality of products regulated by FDA.

ADDRESSES: The "Report of the FDA Task Force on International Harmonization" may be ordered from the National Technical Information Service (NTIS), U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161. Orders must reference NTIS order number PB93–128155 and include payment of $52 for each copy of the document. Payment may be made by check, money order, charge card (American Express, VISA, or MasterCard), or billing arrangements made with NTIS. Charge card orders must include the charge card account number and expiration date. For telephone orders or further information on placing an order, call NTIS at 703–487–4650.

FOR FURTHER INFORMATION CONTACT: Merton V. Smith, Office of Health Affairs (HFY–50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4480.

SUPPLEMENTARY INFORMATION: In December 1991, the Commissioner of Food and Drugs formed the FDA Task Force on International Harmonization to assess the goals, scope, and direction of FDA's participation in international harmonization. Following an indepth study of FDA international activities, including the interviewing of many FDA constituency groups, the task force made eight recommendations for enhancing FDA's international programs.

This report provides an overview of FDA's current international harmonization efforts, describes the importance of assuring consistent scientifically based standards for food, drugs, human biologics, medical devices, and radiation emitting products, and it relates these efforts to the protection of public health. The report also documents the pressures, incentives, and broad public support for active FDA participation in international harmonization programs.

The report is available for purchase from NTIS (address above).

Dated: January 29, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–3041 Filed 2–8–93; 8:45 am]

BILLING CODE 4160–01–F

Public Health Service

Preventive Health Amendments of 1992; Delegation of Authority

Notice is hereby given that in furtherance of the delegation of authority from the Secretary to the Assistant Secretary for Health on January 14, 1981 (46 FR 10016), the Assistant Secretary for Health has delegated to the Director, Centers for Disease Control and Prevention, with authority to redelegate, all the authorities pertaining to the National Foundation for the Centers for Disease Control and Prevention under part N, title III of the Public Health Service Act (42 U.S.C. 241 *et seq.*), as amended. This